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September 6, 2005

## BY FEDERAL EXPRESS

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-820) Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, Maryland 20740

Re: Re-submission of New Dietary Ingredient Notification (NDI) for Kakadu Plum Concentrate

## Dear Sir/Madam:

Pursuant to Section 8 of the Dietary Supplement Health and Education Act of 1994, Access Business Group LLC (ABG), located at 7575 Fulton Street East, Ada, Michigan 49355, re-submits this new dietary ingredient (NDI) notification to the Food and Drug Administration (FDA) for its Kakadu Plum Concentrate product. Three hard copies and an electronic copy of the notification are enclosed.

As recommended by Linda Pellicore and Vickie Lutwak during our March 11, 2005 conference call, this NDI re-submission contains additional information relating the use of kakadu plums in jams and sauces to ABG's product in terms of the number of plums and Vitamin C content. Also included are the methodologies and evidence of actual analytical test results for ABG's product, as well as statements confirming that the actual product reviewed and approved by the TGA is in fact ABG's product and that the test article described in the analytical reports is representative of ABG's product.

2603 MAIN STREET Suite 760 Irvine, California 92614 (949) 553-7400 Fax: 1949) 553-7433 4819 EMPEROR BOULEVARD SUITE 400 DURHAM, NORTH CAROLINA 27703 (919) 313-4750 FAX: (919) 313-4751 Office of Nutritional Products, Labeling and Dietary Supplements December 14, 2004 Page 2

ABG's Kakadu Plum Concentrate is an extract of the kakadu plum that has been concentrated and spray-dried to a powder form. The Australian Therapeutic Goods Administration (TGA) approved ABG's Kakadu Plum Concentrate product for food and dietary supplement use in December of 2003. Kakadu plums have a history of human consumption as a traditional food of the Aboriginal populations in the north and northwestern areas of Australia. The most popular current use for the kakadu plum is in gourmet jams and sauces served in restaurants, airlines and hotels, or sold as specialty foods.

ABG intends to market Kakadu Plum Concentrate as a new dietary ingredient for use in dietary supplements. Specifically, ABG intends to market Kakadu Plum Concentrate, containing 150 to 450 mg. Vitamin C per gram, to dietary supplement manufacturers for use as a natural source of Vitamin C in supplement products at levels consistent with current Vitamin C supplementation practice. ABG anticipates that its Kakadu Plum Concentrate will be used as a source of Vitamin C in supplement products such as multi-vitamin and multi-mineral supplements, Vitamin C supplements, antioxidant supplements, Vitamin C with flavonoids supplements and iron supplements. Such products would be expected to deliver 100 - 800 mg. Kakadu Plum Concentrate per day, providing a daily intake of 15 mg to 360 mg. Vitamin C under the ordinary conditions of intended use of the supplement.

If you have any questions concerning the enclosed NDI re-submission, please contact me as soon as possible by phone (202-737-4291) or by e-mail (dbm@hpm.com).

Sincerely, Diane B. McColl

Diane B. McColl

Counsel to Access Business Group LLC

DBM/csd

Enclosures